Research on Methods – Conceptual Papers

PRM5

INCORPORATING EQUITY INTO DEVELOPING AND IMPLEMENTING EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

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BACKGROUND: Clinical practice guidelines (CPG) are useful tools for clinical decision making, processes standardization and quality of care improvements. The current General Social Security and Health System (GSSHS) in Colombia is promoting the initiative of developing and implementing CPG based on evidence in order to improve efficiency and quality of care. The reduction of inequalities in health should be an objective of the GSSHS. **OBJECTIVES:** The main propose of this analysis is to argue why it is necessary to consider the incorporation of equity considerations in the development and implementation of clinical practice guidelines based on the evidence. **METHODS:** A series of reflections were made. Narrative description was used for showing the arguments that support the main findings. **RESULTS:** Among the main findings are: 1) Differential effectiveness by social groups of interventions could diminish final effectiveness of CPG in the GSSHS; 2) To not consider geographical, ethnic, socioeconomic, cultural and access diversity issues within the CPG could have a potential negative impacts of the CPG; 3) Overall effectiveness of GPC could be better if equity issues are included in the quality verification checklist of the guideline questions; and 4) Incorporating equity issues in the process of developing CPG could be cost effective, because improve overall effectiveness of CPG. **CONCLUSIONS:** To include equity issues in CPG and can help in achieving more equitable health outcomes. From this point of view CPG could be key tools to promote equity in care and health outcomes. Keywords: health inequalities, clinical practice guidelines, essay (Source: MeSH, NLM).

PRM6

TRANSLATION OF PATIENT-REPORTED OUTCOMES MEASURES TRANSLATABILITY REVIEW AND ITEM DEFINITION

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Translatability Review and Item Definition documents are key components to any successful Patient Reported Outcome (PRO) translation and are especially relevant in item banking initiatives. Translatability review helps to ensure concepts, constructs and phrasing in the source language are appropriate for translation into other languages and for multicultural contexts. Identifying potential issues during item development can result in improvement of the source item. When modification of the source is not possible or necessary, translatability review can be seen as a first step towards identifying acceptable translation alternatives which can be used by linguists. The assessment of item translatability before the translation process begins also facilitates the creation of item definitions, a critical tool for increasing translation accuracy. The Item Definition document refers to the identification and clarification of concepts the items are trying to measure. The development of item definitions is an iterative process combining efforts by translation coordinators and item/questionnaire developers as well as input from linguists. These steps are especially essential in item banking initiatives in which items are frequently made available by different developers and sources on behalf of varying patient populations, with disparate answer categories. As translation of PRO measures is much more than just a literal, word for word translation process, these steps are fundamental in furthering the equivalence, comparability and data poolability of translated language versions. This presentation will provide information regarding when to carry out these steps, how to carry them out and who should be involved in them. Linguistic issues such as, but not limited to, sentence structure, register and ambiguity will be discussed. Examples from National Institutes of Health Spanish translation projects Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) and The Patient-Reported Outcomes Measurement Information System (PROMIS) will be highlighted.

Respiratory-Related Disorders – Cost Studies

PRS1

BUDGET IMPACT ANALYSIS OF FLUTICASONE FUROATE (FFNS) IN TREATMENT OF ALLERGIC RHINITIS PATIENTS IN MEXICO

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PRS2

COSTOS DE ATENCION MEDICA ATRIBUIBLES AL CONSUMO DE TABACO EN MÉXICO

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OBJECTIVOS: Estimar la carga económica, en términos de costos de atención médica que las enfermedades atribuibles al consumo de tabaco representan para el sistema de salud Mexicano. **METODOLOGÍAS:** La estimación del costo directo de atención médica atribuible al tabaquismo se realizó con las enfermedades: CP, IAM, EPOC y EVC, en 2009. Instituciones de salud participantes: institutos nacionales (INNN, INCAN, INER e INCAR), Hospital Central Militar (HCM), Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (sólo incluye al CMN "20 de Noviembre" y al HRZ "1°. de Octubre" del ISSSTE) e Instituto Mexicano del Seguro Social (IMSS). El análisis de costos fue realizado desde la perspectiva del proveedor de servicios, utilizando la metodología *Cost of Illness*, basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica: Ambulatoria, Urgencias, Hospitalización, Quirófano, Unidad de Cuidados Intensivos, Quimioterapia, Cuidados Paliativos y Radioterapia. Finalmente empleamos la fracción atribuible por tabaco para estimar dichos costos. Los costos están expresados en pesos mexicanos ($) y en dólares americanos (USD) del 2009. **RESULTADOS:** Los costos institucionales de atención médica por tabaquismo ascendieron a $459,026,446.2 (35,131,636.3 USD); Institutos Nacionales, $92,016,175.0 (7,042,467.4 USD); HCM, $103,483,466.1 (7,920,117.7 USD); ISSSTE y $9,564,089,959.0 (731,988,608.4 USD); IMSS, respectivamente. Los costos nacionales por tabaquismo oscilaron entre $30,213,184,046.5 (2,312,369,147.7 USD) y $44,484,500,278.1 (3,404,625,802.9 USD). El IAM y el CP fueron los más caros. **CONCLUSIONES:** Nuestros resultados muestran la elevada carga económica que representan para el sistema de salud mexicano el tabaquismo y son evidencia científica sobre la magnitud del problema. Como las enfermedades asociadas al tabaquismo son prevenibles, una adecuada política de salud para el control del tabaco, produciría una reasignación de los recursos económicos que actualmente se destinan al tratamiento de las enfermedades provocadas por el tabaco hacia otros programas institucionales.

PRS3

COSTOS DE ATENCION MEDICA DE LA ENFERMEDAD PULMONAR OBSTRUCTIVA CRONICA ATRIBUIBLES AL TABACO

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OBJECTIVOS: Estimar los costos directos de atención médica de la Enfermedad Pulmonar Obstructiva Crónica (EPOC) asociados al consumo de tabaco, en el Instituto Nacional de Enfermedades Respiratorias. **METODOLOGÍAS:** Durante el 2009 se estimaron los costos directos de la EPOC de los pacientes que fueron atendidos en el año 2008 en el Instituto. El análisis de costos se hizo desde la perspectiva del proveedor de servicios, considerando el enfoque de la metodología *Cost of Illness* (COI), basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica en 4 eventos: Ambulatoria, Urgencias, Hospitalización y Unidad de Cuidados Intensivos. Finalmente empleamos la fracción atribuible por tabaco para estimar los costos por consumo de tabaco. El costo además se estimo de acuerdo a la gravedad de la enfermedad con los criterios GOLD. **RESULTADOS:** El costo anual de la EPOC atribuible al tabaco fue de $36 millones. El costo promedio por paciente, de acuerdo a GOLD fue de $30 mil; estadio I, $37 mil; estadio II, $84 mil; estadio III y $288 mil; estadio IV. Entre más grave fue la enfermedad, (III y IV) mayores costos resultaron. **CONCLUSIONES:** La evaluación económica de los costos directos que ocasiona el EPOC debido al tabaquismo, confirma la gran carga económica que representan estos pacientes para el presupuesto del INER y del sistema de salud mexicano. Estos resultados proveen suficiente evidencia científica para apoyar la implementación de políticas del sector salud relacionadas con el tabaco.

PRS4

ECONOMIC EVALUATION OF THE USE OF PALIVIZUMAB AS PROPHYLACTIC TREATMENT FOR THE REDUCTION OF COMPLICATIONS ASSOCIATED WITH RESPIRATORY SYNCYTIAL VIRUS IN PRE-TERM PATIENTS

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OBJECTIVES: To determine the incremental cost-effectiveness ratio (ICER) of the use of palivizumab as prophylaxis for the reduction of complications associated with respiratory syncytial virus (RSV) in pre-term patients <29 weeks of gestational age (WGA) under the Mexican public health sector perspective. **METHODS:** A cost-utility model was developed based on a decision tree that evaluated both scenarios of prophylaxis and no-prophylaxis. Epidemiological and cost data were obtained from different Mexican sources such as the Mexican Institute of Social Security (IMSS) by analysing birth rates. Clinical effectiveness was obtained from the international literature (Cardiac Synagis Study Group, The IMpact-RSV Study Group MEDI-493 Study Group). Prophylaxis therapy consisted of 5 applications of palivizumab during the winter season in Mexico. The dose scheme considered was 15 mg/kg. The effectiveness outcomes were quality adjusted life years (QALYs). Since

the study was conducted under the public health perspective, only direct medical costs associated with the RSV treatment were evaluated (hospitalization, emergency room, drugs, and prophylaxis). For resource utilisation purposes, an expert panel of paediatricians with experience in RSV infection was convened. Drug and medical attention costs were discounted by using a 3% discount rate and are reported in local currency. Acceptability curves of the probability of palivizumab to be cost effective were calculated. The threshold included in the study for cost-effectiveness comparisons, is the proposed by the World Health Organisation (3 times the gross domestic product per capita). **RESULTS:** The ICER per QALY for the study group was MXN $219,150. The acceptability curves showed a 75% probability of palivizumab to be cost effective when employing a 3 times GDP threshold. **CONCLUSIONS:** The use of palivizumab represents a cost-effective alternative for the prophylaxis of complications associated with RSV infection, under the public health perspective in Mexico for patients <29 WGA.

PRS5

COST-EFFECTIVENESS OF VARENICLINE VS EXISTING SMOKING CESSATION STRATEGIES IN DOMINICAN REPUBLIC USING THE BENESCO MODEL

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OBJECTIVES: In Dominican Republic, the economic burden of tobacco has not been assessed. The aim of this study was to evaluate the cost-effectiveness of varenicline compared to other existing strategies for smoking cessation within a 5-year time horizon in an adult population cohort from Dominican Republic using the healthcare payer's perspective. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an adult cohort in Dominican Republic (n=6,528,125). Smoking cessation therapies compared were: varenicline (0.5 – 2 mg/day) versus bupropion (300 mg/day); nicotine replacement treatment (NRT) (5-10 mg/day) and unaided cessation. Effectiveness measures were: Life-Year gained (LYG) and quality-adjusted life-year gained (QALY's). Resource use and costs data were obtained from Dominican Republic's Ministry of Health and Social Security databases (2009). The model used a 3% discount rate for costs (expressed in 2009 US dollars) and health outcomes. Probabilistic sensitivity analyses (PSA) were conducted and acceptability curves were constructed. **RESULTS:** Varenicline reduced smoking-related morbidity, mortality and healthcare costs. After 5 years, mortality in the varenicline arm was reduced by 67, 86 and 163 deaths compared with bupropion, NRT and unaided cessation, respectively. The net average cost per additional quitter showed that varenicline was cost-saving against competing alternatives. Varenicline exhibited 145, 188 and 355 more QALYs against Bupropion, NRT and unaided cessation, respectively. Cost-effectiveness analyses showed that varenicline was the dominant strategy. At a willingness-to-pay of US$8,000/QALY, the probability that varenicline is cost-effective met 100%. PSA results support the robustness of the findings. **CONCLUSIONS:** Smoking cessation therapy with varenicline is cost-saving in Dominican Republic. These results could help to reduce the tobacco related disease burden and align cost-containment policies.

PRS6

COST-EFFECTIVENESS OF FLUTICASONE FUROATE COMPARED WITH MOMETASONA FUROATE FOR THE PRIMARY TREATMENT OF ALLERGIC RHINITIS PATIENTS

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OBJECTIVES: To evaluate the cost-effectiveness of fluticasone furoate vs. mometasone furoate in the treatment of ocular symptoms in allergic rhinitis patients in Mexico. **METHODS:** A decision-analytic model was developed to estimate the cost-effectiveness of fluticasone furoate versus mometasone furoate. Patients initiated on treatment either completed initial therapy or switched to second line therapy due to non-response. Probability of a switch and resource use was based on expert panel and literature. Costs were based on local drug acquisition costs, local cost estimates for outpatient and hospitalization. Effectiveness was defined as the net improvement in Total Ocular Symptom Score (TOSS) at 12 weeks from Keith PK. 2009 study. The analysis was carried out from the perspective of the Mexican health care system and all costs are reported in 2010 US dollars. **RESULTS:** The corresponding health effects were 0.47 net improvement TOSS for fluticaone furoate and 0.31 for mometasone furoate regimen. The mean total cost of the fluticaone furoate regimen was $ 627 compared with $ 827 for the furoate mometasone regimen. Treatment with fluticasone furoate compared to treatment with mometasone furoate was less costly and resulted in a greater net improvement of TOSS. Probabilistic sensitivity analyses demonstrated that the cost savings observed were maintained over a wide range of alternative values for costs and resource utilization. **CONCLUSIONS:** Cost-effectiveness analysis indicated the dominance of fluticasone furoate over mometasone furoate because of both lower costs and greater efficacy. Cost savings with fluticasone furoate were attributable to lower drug acquisition costs. In addition, a net improvement in ocular symptoms may be expected in allergic rhinitis patients.

PRS7

ESTUDIO DE COSTO-EFECTIVIDAD DE BECLOMETASONA VS CICLESONIDA COMO MEDICAMENTOS CONTROLADORES EN EL MANEJO DEL ASMA EN PACIENTES QUE ASISTEN A CONSULTA EXTERNA DE NEUMOLOGÍA PEDIÁTRICA EN EL HOSPITAL UNIVERSITARIO CLÍNICA SAN RAFAEL DE BOGOTÁ COLOMBIA, JULIO A DICIEMBRE 2010

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OBJECTIVOS: Desarrollar un estudio de costo-efectividad que compare Ciclesonida con Beclometasona en el control del asma. **METODOLOGÍAS:** Estudio Costo-Efectividad, de cohortes, observacional, analítico, con información recolectada prospectivamente, realizado desde la perspectiva institucional, incluyó pacientes pediátricos con diagnóstico de asma no controlada admitidos durante Julio de 2010 los que recibieron Ciclesonida o Beclometasona como único medicamento controlador. Se realizó seguimiento por 6 meses, basados en datos reportados por la literatura se utilizó el porcentaje de pacientes libres de crisis asmáticas como variable para el cálculo del tamaño muestral, la muestra necesaria fué de 20 pacientes por cada alternativa, se incluyeron 94 pacientes con edades entre los 1 y 15 años, 47 recibieron Beclometasona y 47 Ciclesonida. La asignación fue de manera aleatoria. La variable primaria de efectividad fue definida como el porcentaje de pacientes libres de crisis durante el periodo de estudio, se definieron como variables generadoras de costo uso de medicamentos y estancia hospitalaria. Se calculó la razón costo-efectividad incremental y se realizó un modelo mediante un árbol de decisión. **RESULTADOS:** 17 pacientes estuvieron libres de crisis en el grupo de Beclometasona, los costos de utilización de medicamentos en este grupo fueron de $7255.564 pesos colombianos, los costos de hospitalización se calcularon en $38,568.200, los costos totales ascendieron a $45,823.764 ($25,188.67 dólares). En el grupo de Ciclesonida, 45 pacientes estuvieron libres de crisis, los costos por utilización de medicamentos fueron de $14,982.172, los costos derivados de hospitalización se calcularon en $92,200, los costos totales alcanzaron los $15,074.372 ($8291.73 dólares). La razón costo-efectividad incremental de Beclometasona versus Ciclesonida fue de -1'098.192. **CONCLUSIONES:** Al utilizar Ciclesonida el hospital encuentra ahorros de $1098.192 pesos por cada paciente libre de crisis, desde la perspectiva del hospital, el manejar un paciente con Beclometasona representa un costo adicional de $1,098.192 que se podrían ahorrar si el paciente fuese manejado con Ciclesonida.

PRS8

COST-EFFECTIVENESS OF AN AMBULATORY PROGRAM OF PULMONARY REHABILITATION FOLLOWING ACUTE EXACERBATIONS OF COPD IN COLOMBIA

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OBJECTIVES: To evaluate the economic benefits of an 8 week Ambulatory Pulmonary Rehabilitation Program (PR) plus GOLD based standard treatment (ST) vs. ST without PR of COPD patients after an acute exacerbation of the disease in the Colombian Health Care System (CHCS). **METHODS:** Direct costs of ST and of PR were calculated according to tertiary level university hospital's registries during one year and CHCS's drugs prices; these costs and QALY were estimated for one year by a Markov chain model based on Seymour's study (Thorax, 2010) findings of health care utilization and probability of death. Univariate sensitivity and probabilistic analysis were performed by Monte Carlo method. **RESULTS:** Following acute exacerbation of COPD the annual cost of PR plus ST was COL$ 4,594,407,00 (US$ 2,483.46) vs. an annual cost of ST without PR of COL$ 9,124,326.00 (US$ 4,932.07). QALY of PR plus ST patients: 0.86577; QALY of ST without PR: 0.852979. Mean cost-effectiveness of PR plus ST: COL$5,306,729.00 (US$ 2,868.50) per QALY, cost-effectiveness of ST without PR:$10,697,014.00 (US$ 5,782.17) per QALY. There was absolute dominance of PR plus ST vs. ST without PR in all scenarios. In the sensitivity analysis the absolute dominance is maintained for any cost of PR program < COL$ 5,302,428.00 (US$ 2.866,18). **CONCLUSIONS:** Global costs of Pulmonary Rehabilitation plus Standard Treatment are much lower than Standard Treatment without Pulmonary Rehabilitation for patients after an acute exacerbation of COPD. Pulmonary Rehabilitation is a highly cost-effective treatment for these patients in the CHCS and probably in many other countries with similar socio-economic level, specially of Latin America.

Respiratory-Related Disorders – Patient-Reported Outcomes & Preference-Based Studies

PRS9

DISPONIBILIDAD A PAGAR POR UN METODO EFECTIVO PARA DEJAR DE FUMAR: EVIDENCIAS A PARTIR DE LA ENCUESTA GLOBAL DE TABAQUISMO EN ADULTOS MÉXICO 2009

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OBJECTIVOS: Estimar la máxima disponibilidad a pagar (DAP) por un tratamiento efectivo de cesación tabáquica entre fumadores mexicanos e identificar los factores sociodemográficos, de la historia de fumador y de su entorno asociados a esta valoración. **METODOLOGÍAS:** Se realizó un estudio observacional de tipo transversal. La muestra de análisis estuvo constituida por 777 fumadores que participaron en la Encuesta Global de Tabaquismo en Adultos, México 2009. Se realizó un análisis descriptivo y de asociación estadística que permitió caracterizar a los fumadores y su DAP con base en variables socioeconómicas, demográficas, de su historia de tabaquismo y de su entorno. **RESULTADOS:** El 74.4% de los fumadores eran del sexo masculino, 51.4% consumía cigarrillos con una frecuencia diaria. Los fumadores tenían más de 15 años fumando, 58.6% había realizado intentos previos de cesación y alrededor del 10% conocía de la existencia de centros de ayuda para dejar de fumar. En promedio, la DAP por un método efectivo de cesación fue $2573 pesos mexicanos. En los hombres, la DAP fue 2056 pesos menor que en las mujeres. A mayor educación y mayor nivel socioeconómico (NSE), la DAP de los fumadores aumentó en todos los modelos estimados. **CONCLUSIONES:** Las estimaciones del presente estudio sugieren que los fumadores mexicanos que desean dejar de fumar revelan, en términos monetarios, una alta valoración por un método de cesación efectivo. Los fumadores del sexo masculino muestran un comportamiento